

Exhibit B

(Part 2 of 2)

gene. This information would have been material to the examination and/or patentability of the claims of the prior issued Axel patents and the '275 patent for reasons discussed below.

46. During prosecution of the '665 patent, in an August 12, 1985 Office Action, the examiner rejected claim 153. In asserting that the claim was unpatentable over Willecke *et al.* 1976 in view of Nunberg *et al.*, the examiner noted that Willecke *et al.* 1976 "teach the cotransfer of two linked genes into cultured mouse cells using one gene coding for a selectable trait and producing proteins from each gene." One of the genes cotransferred by Willecke *et al.* as reported in Willecke *et al.* 1976 was the *tk* gene. The examiner cited Nunberg *et al.* as showing "increased synthesis of reductase and the gene copy number in cultured mouse cells . . ."

47. As discussed above in ¶ 38(b), Columbia's February 11, 1986 Response to the rejection based on Willecke *et al.* 1976 and Nunberg *et al.* attempted to distinguish claims prosecuted during the '665 patent prosecution on the basis that "Willecke *et al.* do not teach or suggest the use of a DNA II which encodes an amplifiable gene for a dominant selectable phenotype as a means of identifying eucaryotic cells which have been amplified to contain multiple copies of a foreign DNA I." This distinction was misleading in view of Axel's own work. Disclosure of Axel 1982 and 1983 would have alerted the examiner that Axel had demonstrated that the *tk* gene was a selectable, inherently amplifiable, marker. Axel's 1982 and 1983 publications were therefore material to the patentability of the claims rejected by the '665 patent examiner, and the claims in the '216 patent which could also have been rejected based on Willecke *et al.* 1976, as discussed above in ¶ 38(b).

48. Columbia continued to fail to disclose the amplifiability of the *tk* gene uscd by Willecke *et al.* 1976 during the prosecution of the '275 patent. During prosecution of the '275 patent, Columbia filed new claim 141 in its June 14, 2001 amendment. As originally filed, claim 141 was substantially similar to the claims rejected on August 12, 1985 in the '665 prosecution as obvious in view of Willecke *et al.* 1976. The Axel 1982 and 1983 publications were also at

least as material to the examination and patentability of claim 141 which issued as claim 2 in the '275 patent as they were to the patentability of claims 153-155 in the '665 prosecution.

(iii) Columbia also failed to disclose co-owned U.S. Patent No. 5,149,636 and its prosecution history

49. During the prosecution of the Axel patents, Columbia also filed a separate U.S. patent application, U.S. Ser. No. 358,206 (the '636 patent application), on March 15, 1982. Columbia named Richard Axel and another Columbia employee, James M. Roberts, as inventors on the '636 patent application, which was entitled, "Method for Introducing Cloned, Amplifiable Genes into Eucaryotic Cells and for Producing Proteinaceous Products." After filing several continuation applications, the '636 patent application eventually led to the issuance of U.S. Patent No. 5,149,636 ("the '636 patent") on September 22, 1992. The same law firm prosecuted both the applications giving rise to the '636 patent and the Axel patents. In addition, both patents name Richard Axel as a co-inventor.

50. During prosecution of the '636 patent, Columbia pursued claims similar to those pursued and issued in the '216 and '275 patents, and the examiner rejected claims as anticipated or obvious based on the '216 patent. Despite these similarities, Columbia failed to disclose the '636 patent or its prosecution to the examiners of the '216, '665, '017 or '275 patents. On April 15, 1983, the examiner of the '636 patent rejected all the claims as anticipated by, or obvious in view of Axel *et al.*, WO81/02426, the published foreign PCT application corresponding to the '216 patent, and further advised Columbia "to provide a clear line of demarcation between the claims of the subject invention and their other copending applications."

51. In an August 15, 1983 response, Columbia acknowledged "the Examiner's admonition," and affirmatively asserted it was maintaining a demarcation between the claims in the '636 patent application and the Axel *et al.* line of applications. The examiner disagreed, maintaining the rejection. In addition, upon learning of the issuance of the '216 patent, in a June 3, 1986 Office Action, another '636 patent examiner rejected transformed cell claims as

anticipated by the '216 patent, and concluded that the '216 patent "claim[s] the same invention and use[s] the same genes as in the instant application." The examiner maintained the rejection in a March 24, 1988 Office Action.

52. The '636 examiner's conclusion that the '216 patent and the '636 patent claim the same invention illustrates the substantial similarity of the '216 patent claims to the rejected claims. Since the claims in the '216 patent are substantially similar to claims Columbia pursued and obtained during the '275 patent prosecution, the '636 patent prosecution was material to the examination and/or patentability of the Axel patents.

29. (iv) During the prosecution of the '275 patent and its patent family,

Columbia made several additional misrepresentations and misleading omissions that were material to the patentability of the '275 patent, including misrepresenting the scope of the '216 patent

(i) — Columbia misrepresented the scope of the '216 patent and misled the patent examiner

53. **30.** On November 5, 1981, in response to a prior art rejection of the claims in the application which matured into the '216 patent, Columbia submitted declarations in an effort to distinguish Mantei *et al.* (1979) "Rabbit β -globin mRNA production in mouse L cells transformed with cloned rabbit β -globin chromosomal DNA," Nature 281:40-46, from the claims. Columbia argued that the claims were patentably distinct from the transformation with linked DNA disclosed by Mantei *et al.* Almost 19 years later, through the same counsel who distinguished Mantei *et al.*, on July 31, 2000 (just as the '216 patent was about to expire), Columbia knowingly and with an intent to deceive, contradicted its earlier statement to the PTO during its effort to secure the '275 patent. In responding to an Office Action rejection, Columbia distinguished the '216 patent claims on the basis that they covered transformation with both linked and unlinked DNA. These contradictory statements were material.

54. 31. In addition, Columbia made false and misleading statements in its June 14, 2001 and January 30, 2002 remarks in order to distinguish the newly filed claims of the '275 patent application from the claims of the '216 patent. First, Columbia stated that "none of the claims of the '216 [patent] make obvious a recitation of 'linked'" DNA (DNA I and DNA II) in the '275 patent claims. In fact, claim 54 of the '216 patent recites transforming a eucaryotic cell with a DNA "formed by linking one of said foreign DNA I molecules to a DNA II molecule."

55. 32. Second, Columbia told the PTO on June 14, 2001 and again on January 30, 2002 that "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, claim 54 of the '216 patent also recites transforming a cell with DNA I linked to a "DNA II corresponding to an amplifiable gene," and further provides "culturing the transformed eucaryotic cells in the presence of successively elevated concentrations of an agent permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene."

56. 33. Because DNA I and DNA II are linked ~~prior to transformation~~, this process would be expected to produce transformed cells in which DNA I was also amplified. Indeed, Columbia had earlier told Congress—but not the examiner—that amplification of both DNA I ~~& and~~ II was the result of this process. Columbia's misrepresentations, made to secure allowance of the '275 patent, were material ~~and they were knowingly misleading and inaccurate to the examination and patentability of the '275 patent.~~

(iii)-(v) Columbia failed to disclose statements made to Congress that contradicted or rebutted positions taken during prosecution of the '275 patent

57. 34. Columbia further failed to disclose statements made to Congress regarding the breadth of the '216 patent, which contradicted the misrepresentations made during the '275 patent prosecution.

58. 35. In its efforts to convince Congress that the '216 patent was a pioneering, broad patent meriting a legislative extension, Columbia made statements regarding the breadth and coverage of the '216 patent that contradicted misrepresentations that Columbia later made during prosecution of the '275 patent.

59. 36. For example, in describing "Columbia University's Cotransformation Patent," Columbia told Congress that the '216 patent covered both "unlinked" transformation and "linked" transformation where a selectable marker (DNA II) and the gene encoding the protein of interest (DNA I) are "joined together in a single DNA construct prior to their introduction into the cell." Columbia failed to disclose its statement to Congress to the PTO when it later distinguished the claims of the '275 patent from the claims of the '216 patent by stating just the opposite: "none of the claims of the '216 [patent] make obvious a recitation of 'linked'" DNA.

60. 37. Columbia also told Congress that the process of the '216 patent could be used "to introduce an amplifiable marker gene" into a cell, "whose numbers can be increased after the initial selection event in response to increasing the concentration of the toxic selective agent. In this way, the number of copies of both the selectable marker and the linked gene of interest are amplified." Again, Columbia contradicted these statements in representations it later made to the PTO. In fact, Columbia stated that "none of the claims of the '216 [patent] make obvious a recitation that both DNA I and DNA II are amplified."

61. 38. Columbia owed a duty to the PTO to disclose its prior statements made to Congress that tended to refute or were inconsistent with positions it was taking during prosecution of the '275 patent. Nonetheless, Columbia failed to tell the PTO about its earlier attempts to obtain a legislative patent term extension of the '216 patent and the representations it had made to Congress regarding the scope of the '216 patent. ~~Columbia's failure to disclose with intent to deceive these material statements it made to Congress, constitutes~~

~~inequitable conduct. This information would have been material to the examination and/or patentability of the '275 patent.~~

(iii)-(vi) Columbia misled the '275 patent examiner into withdrawing double-patenting rejections based on the '017 patent

62. **39.** Another example of Columbia's misrepresentations and misleading statements to the PTO began with the PTO examiner's February 3, 1998 rejection of all pending claims in the application leading to the '275 patent, and his identifying as the basis for the rejection "double patenting" with reference to the transformed Chinese Hamster Ovary ("CHO") cell claims of the '017 patent.

63. **40.** On July 24, 1998, Columbia responded to this rejection by canceling the only transformed cell claim; and by conceding the merits of the PTO examiner's double patenting rejection for this claim in its response. Columbia also argued that the remaining claims were now distinct from the transformed cells claimed in the '017 patent.

64. **41.** On September 14, 1998, the PTO examiner accepted this argument, but rejected the remaining proposed claims on other grounds, and Columbia proceeded with the prosecution.

65. **42.** On January 31, 2000, after a new PTO examiner was assigned to the prosecution, and again on October 24, 2000, the pending proposed claims—which did not include claims to transformed CHO cells—were rejected, and ~~the~~one identified basis for rejection was again "double patenting," this time with reference to the claims of the '216 patent.

66. **43.** On June 14, 2001, Columbia responded to these rejections, in part by adding new claims like the previously-rejected and then-canceled transformed cell claim. The claims were added by the same prosecuting counsel who had responded to the February 3, 1998 rejection by a different examiner. But in adding these new claims ~~he, counsel~~ failed to call to the new PTO examiner's attention the rejection of February 3, 1998 and ~~his~~the earlier response of July 24, 1998.

67. **44.** Instead, Columbia limited its prospective arguments that the new claims were free from a double-patenting rejection to distinctions between the new claims and the '216 patent claims. Even though some of the new claims related to transformed CHO cells, Columbia failed to raise the previous Examinerexaminer's rejections of transformed cell claims in view of the '017 patent. Columbia's statements and omissions were material and misleading, because, among other things, they suggested that the '216 patent was the only basis for a double-patenting rejection and ignored the prior double patenting rejection based on the '017 patent. In fact, the Examinerexaminer was misled, as he relied only on the '216 patent as a basis for a double-patenting rejection. As a result of Columbia's manipulation of the process, and its non-disclosures and misleading statements, Columbia obtained the '275 patent.

(iv)-(vii) During prosecution of the '275 patent, Columbia further misled the examiners to avoid double-patenting rejections based on the '017 patent

68. **45.** To avoid double-patenting rejections based on the '017 patent, Columbia further misled the examiners of the '275 patent regarding the related application, U.S. Application Ser. No. 08/477,159 ("the '159 application") which it still has pending in the PTO. The '159 application was filed and prosecuted by the same attorney and law firm that filed the '275 patent, and claims priority to the same application first filed in February 1980.

69. **46.** On April 29, 1997, the examiner of the '159 application rejected claim 135, for obviousness-type double patenting in view of claims in the '017 patent. Claim 135 was drawn to a method of producing a proteinaceous material by culturing CHO cells. Columbia failed to overcome the '159 examiner's double-patenting rejection of claim 135 and canceled the claim on August 24, 1998.

70. **47.** When Columbia cancelled claim 135 in the '159 application, the examiner of the '275 application, was maintaining double-patenting rejections of the then-pending claims in view of the '017 patent. Nearly three years after canceling claim 135 in the '159 application,

when the examiner of the '275 patent had changed from the one who had rejected claim 135 in the '159 application, Columbia added a corresponding claim in the '275 patent prosecution. Specifically, on June 14, 2001, when Columbia's other PTO maneuvers had misled the '275 patent examiner into withdrawing rejections based on the '017 patent, Columbia added to the '275 patent prosecution a claim substantially similar to the claim cancelled in the '159 application because of the '017 double-patenting rejection.

71. ~~48.~~ This added claim issued as claim 14 in the '275 patent. By the time Columbia added claim 14, a different examiner was examining the '275 patent application, and the new examiner was relying only on the '216 patent as the basis for double-patenting rejections. By canceling claim 135 in the '159 application and waiting three years to file claim 14 in the '275 patent, Columbia manipulated the patent process and misled the examiners of the '275 patent to avoid a double-patenting rejection of claim 14 based on the '017 patent, as it had received in the parallel '159 prosecution.

72. ~~49.~~ In addition, Columbia did not bring the existence of the '159 application to the '275 examiner's attention until May 6, 2002—~~almost~~ seven years after the two applications had been filed. Even then, Columbia failed to specifically point out the '159 examiner's rejection of claim 135, substantially similar to claim 14, as obvious in view of the claims of the '017 patent. The rejection of claim 135 during the prosecution of the '159 application was material to the ~~prosecution of the '275 patent, examination and patentability of the '275 patent.~~

~~(v) Columbia failed to disclose publications co-authored by named inventors~~

~~50.~~ ~~Columbia further failed to disclose to the '275 patent examiners later publications co-authored by Axel. The publications included Roberts & Axel, "Gene Amplification and Gene Correction in Somatic Cells," Cell 29:109-119 (1982) (hereinafter "Axel 1982") and follow-up studies reported in Roberts, Buck~~

~~& Axel, Cell 33:53-63 (1983) (hereinafter "Axel 1983"). These publications described cell transformation using a promoterless *tk* gene as the selectable marker. Axel 1982 showed that the promoterless *tk* gene was an amplifiable gene, while Axel 1983 described the results of studies on the structure of amplified units of DNA following transformation and amplification of the promoterless *tk* gene. This information would have been material to the patentability of the '275 patent claims for reasons discussed below.~~

51. During prosecution of the '665 patent, in an August 12, 1985 Office Action, the examiner rejected claim 153. In asserting that the claim was unpatentable over Willecke *et al.*, PNAS 73(4) 1274-78 (1976) in view of Nunberg *et al.*, PNAS 75(11) 5553-5556 (1978), the examiner noted that Willecke *et al.* "teach the cotransfer of two linked genes into cultured mouse cells using one gene coding for a selectable trait and producing proteins from each gene." One of the genes cotransferred by Willecke *et al.* was the *tk* gene. The examiner cited Nunberg as showing "increased synthesis of reductase and the gene copy number in cultured mouse cells . . ."

52. In a February 11, 1986 Response, Columbia distinguished Willecke *et al.* on the basis that "Willecke *et al.* do not teach or suggest the use of a DNA II which encodes an amplifiable gene for a dominant selectable phenotype as a means of identifying eucaryotic cells which have been amplified to contain multiple copies of a foreign DNA I." This statement made to distinguish Willecke *et al.* was misleading in view of Axel's own work. Disclosure of Axel 1982 and 1983 would have alerted the examiner that Axel had demonstrated that the *tk* gene was a selectable, inherently amplifiable, marker. Axel's 1982 and 1983 publications were therefore material to the patentability of the claim rejected by the '665 patent examiner.

53. During prosecution of the '275 patent, Columbia filed new claim 141 in its June 14, 2001 amendment. As originally filed, claim 141 was substantially similar to the claim rejected on August 12, 1985 in the '665 prosecution as obvious in view of Willecke *et al.* The Axel 1982 and 1983 publications were also material to the patentability of claim 141 which issued as claim 2 in the '275 patent, as they were material to the patentability of claim 153 in the '665 prosecution. Columbia's failure to disclose the Axel 1982 and 1983 references during prosecution of the '275 patent therefore breached its duty to disclose material information to the Patent Office.

(vi) Columbia also failed to disclose co-owned U.S. Patent No. 5,149,636, and its prosecution history

54. During the prosecution of the '275 patent family, Columbia also filed a separate U.S. patent application, U.S. Ser. No. 358,206 (the '636 patent application), on March 15, 1982. Columbia named Richard Axel and another Columbia employee, James M. Roberts, as inventors on the '636 patent application, which was entitled, "Method for Introducing Cloned, Amplifiable Genes into Eucaryotic Cells and for Producing Proteinaceous Products." After filing several continuation applications, the '636 patent application eventually led to the issuance of U.S. Patent No. 5,149,636 ("the '636 patent") on September 22, 1992. The same law firm prosecuted both the applications giving rise to the '636 patent and the '275 patent. In addition, both patents name Richard Axel as a co-inventor.

55. During prosecution of the '636 patent, Columbia pursued claims similar to those pursued and issued in the '216 and '275 patents, and the examiner rejected claims as anticipated or obvious based on the '216 patent. Despite these similarities, Columbia failed to disclose the '636 patent or its prosecution to any of

~~the '275 patent examiners, none of whom examined the '636 patent. On April 15, 1983, the examiner of the '636 patent rejected all the claims as anticipated by, or obvious in view of Axel et al., WO81/02425, the published foreign PCT application corresponding to the '216 patent, and further advised Columbia "to provide a clear line of demarcation between the claims of the subject invention and their other copending applications."~~

~~56. In an August 15, 1983 response, Columbia acknowledged "the Examiner's admonition," and affirmatively asserted it was maintaining a demarcation between the claims in the '636 patent application and the Axel et al. line of applications. The examiner disagreed, maintaining the rejection. In addition, upon learning of the issuance of the '216 patent, in a June 3, 1986 Office Action, another '636 patent examiner rejected transformed cell claims as anticipated by the '216 patent, and concluded that the '216 patent "claim[s] the same invention and use[s] the same genes as in the instant application." The examiner maintained the rejection in a March 24, 1988 Office Action.~~

~~57. The '636 examiner's conclusion that the '216 patent and the '636 patent claim the same invention illustrates the substantial similarity of the '216 patent claims to the rejected claims. Since the claims in the '216 patent are substantially similar to claims Columbia pursued and obtained during the '275 patent prosecution, the '636 patent prosecution was material to the '275 prosecution.~~

F. Columbia's Demand for Royalties and Fees

F. Columbia's Allegations that the Prior Issued Axel Patents and the '275 Patent Cover Activities of Plaintiffs

~~73. 58. By letters of January 26, 2001, December 5, 2001, December 28, 2001 and June 14, 2002, and November 12, 2002, and November 26, 2002, Columbia has demonstrated its~~

intention to enforce the prior issued Axel patents and the '275 patent against the activities of Amgen and Immunex. It has:

- (a) Made~~made~~ demand upon Amgen and Immunex ~~in the name of~~ ~~under~~ the License Agreement, for the payment of royalties for sales occurring after August 16, 2000, ~~even though the '216, '665 and '017 patents had expired~~ ~~and before the issuance of the '275 patent, based on the expired prior issued Axel patents;~~
- (b) Asserted~~asserted~~ to Amgen and Immunex, in this regard, *inter alia*, that Columbia had pending patent applications after August 16, 2000, as a result of which Columbia demanded that Amgen pay royalties on sales after August 16, 2000;
- (c) Asserted~~asserted~~ further that Amgen was breaching the License Agreement through non-payment of royalties;
- (d) Specified~~specified~~ the '275 patent, once issued on September 24, 2002, as being part of the Licensed Patent Rights under the License Agreement; ~~and~~
- (e) Provided~~provided~~ further "notification" to Immunex, regarding the '275 patent, including a copy of a reported District Court decision regarding enforcement of the first '216 patent, with the comment that in certain instances "Columbia will reluctantly be forced to consider alternative approaches.";
- (f) filed counterclaims against Amgen and Immunex, alleging that their activities are covered by one or more claims of the '275 patent.

G. Columbia's Purported Termination of the License Agreement and Its Litigation Tactics

74. The license agreement between Columbia and Immunex expired on January 4, 2003, and thereafter the license agreement between Columbia and Amgen Inc. covered Immunex as well as Amgen Inc.'s other affiliates. However, on March 9, 2004, Columbia purported to terminate its license agreement with Amgen. In light of Columbia's assertions that the conduct of Amgen and Immunex was covered by the License Agreement, this purported termination

further demonstrates Columbia's intention to enforce the '275 patent against Amgen and is wrongful in light of Columbia's conduct in connection with all of the patents discussed above.

75. In response to this action to determine the invalidity and unenforceability of the '275 patent, Columbia attempted to avoid and delay the determination of these issues. Toward that end, Columbia filed an application in the PTO seeking reissue of the patent, and based on that application, sought a stay of the litigation (which was denied). When confronted with deadlines for exchange of expert evidence that would evidence the invalidity of the '275 patent because of double-patenting (evidence that Columbia would then be obliged to disclose to the PTO in the reissue proceeding), and approximately two weeks following the Court's Order of August 17, 2004 in this action allowing certain depositions of percipient witnesses whose testimony was to be completed by September 30, 2004 and whose testimony would further evidence Columbia's inequitable conduct, Columbia filed on September 2, 2004, an "emergency motion" to dismiss the challenges to the '275 patent based on a covenant not to sue (the "Covenant") which Columbia contended to mean that there was no longer a case or controversy regarding the challenges to the '275 patent. Columbia's original Covenant was so transparently defective that Columbia has extended it in several ways. However, Columbia has failed and refused to extend the Covenant to include the claims of the '275 patent if they emerge as part of a different patent (for which Columbia has the '159 application pending) or to Amgen's affiliates.

FIRST CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Owe No Royalties , that the License Agreement has not been Validly Terminated, and to Recover Overpaid Royalties

(28 U.S. C. § 2201)

76. 59. Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-58,75, inclusive, as if fully set forth herein.

77. ~~60.~~ An actual controversy has arisen and now exists between Plaintiffs, on the one hand, and Columbia, on the other hand, concerning whether, as Columbia contends, Plaintiffs are breaching the License Agreement by non-payment of royalties for periods after August 16, 2000.

78. ~~61.~~ Immunex is informed and believes and on such information and belief alleges that Columbia contends that Immunex must pay royalties and a fee for periods after August 16, 2000 because, *inter alia*, ~~claims in pending patent applications, including the application leading to the '275 patent, were pending after August 16, 2000 and further contends that the pending patent applications covered at least one Immunex product when the prior issued Axel patents expired because, inter alia, an Immunex product was covered by enforceable claims of the Licensed Patent Rights described in the License Agreement.~~ Immunex contends that it is not required to pay royalties and fees for periods after August 16, 2000, because, *inter alia*, ~~the pendency of those patent applications does and the above-mentioned patents did not result in Immunex's products qualifying as Licensed Products, the sale of which would trigger a royalty obligation under the License Agreement, Exhibit FE.~~ On the contrary, Immunex by mistake paid royalties on Enbrel® (etanercept) and such overpaid amounts should be repaid by Columbia, with interest.

79. ~~62.~~ Amgen is informed and believes and on such information and belief alleges that Columbia contends that Amgen must pay royalties and fees for periods after August 16, 2000 because, *inter alia*, ~~claims in pending patent applications, including the application leading to the '275 patent, were pending after August 16, 2000 and further contends that the pending patent applications covered one or more of the products of Amgen certain Amgen products were covered by enforceable claims of the Licensed Patent Rights described in the License Agreement.~~ Amgen contends that it is not required to pay royalties and fees for periods after August 16, 2000 because, *inter alia*, ~~the pendency of those applications does not result in Amgen's products qualifying as~~

Licensed Products, the sale of which would trigger a royalty obligation when the prior issued Axel patents expired, because, *inter alia*, no such products were covered by enforceable claims of the Licensed Patent Rights under the License Agreement, Exhibit E.D. On the contrary, pursuant to Section 3(j) of the License Agreement, “If Columbia, under substantially identical conditions, grants to a third party a license under Licensed Patent Rights, having royalty rates more favorable to such third party than those set forth herein, Columbia will give [Amgen] the benefit of such rates.” Amgen has now learned that Columbia, without disclosure to Amgen, entered into just such a license effective July 31, 1990 with Genetics Institute, Inc. (“GI”), pursuant to which the royalty rates were more favorable to GI. In particular, Amgen’s License Agreement provides in part (Section 3(i)):

If the manufacture, use or sale by Licensee of a Licensed Product in any country where Licensed Patent Rights exist would infringe a patent in that country, which patent is owned by a third party, Licensee shall be entitled to deduct from the royalties due from Licensee to Columbia based upon sales of such Licensed Products in such country certain royalties paid by Licensee to such third party for a license under such patent. Specifically, Licensee may deduct from the royalties due from Licensee to Columbia based upon sales of such Licensed Product in such country up to one-third of the royalties paid by Licensee to such third party based upon such sales, provided such deductions shall not exceed one-third of the amount of royalties due from Licensee to Columbia on such sales.

However, in Columbia’s license to GI, the phrase “up to one-third of the royalties paid by Licensee to such third party based upon such sales,” was stricken, thus lowering GI’s royalty rate. Because of Columbia’s failure to disclose the more favorable royalty rate granted to GI, Amgen overpaid royalties to Columbia by mistake, and Amgen seeks in this action to recover such overpaid royalties, with interest.

80. Additionally, any claim to additional royalties by Columbia is unlawful and barred by its own unclean hands in and about the matters relating to the Axel patents and the

licenses thereof, as a result of which none of the royalties or amounts claimed by Columbia are in fact owed, and Columbia's purported termination is invalid and ineffective.

81. ~~63.~~ Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

SECOND CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty Obligations Because the '275 Patent Is Invalid By Reason of Double -Patenting and Statutory Grounds

(28 U.S.C. § 2201)

82. ~~64.~~ Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1- ~~63,81~~ inclusive, as if fully set forth herein.

83. ~~65.~~ An actual controversy has arisen and now exists between Plaintiffs, on the one hand, and Columbia, on the other hand, concerning whether, as Columbia contends, Plaintiffs have breached, and are breaching the License Agreement by non-payment of royalties for periods after August 16, 2000.

84. ~~66.~~ Plaintiffs are informed, and believe, and on such information and belief allege, that Columbia contends that Plaintiffs must pay royalties for periods after August 16, 2000 because the '275 patent, when issued on September 24, 2002, covered some or all of the products of Plaintiffs. Plaintiffs contend that they are not required to pay royalties for periods after September 24, 2002 because the '275 patent is invalid for double -patenting and for failing to satisfy one or more of the conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103 and 112.

85. ~~67.~~ Plaintiffs desire a judicial determination and declaration that they do not owe the royalties claimed by Columbia, because each of the '275 patent claims is essentially identical to or an obvious variation of the claims of the '216, '665 and/or '017 patents, and therefore the '275 patent is invalid for double -patenting.

86. ~~68.~~ Plaintiffs desire a judicial determination and declaration that they do not owe the royalties claimed by Columbia because the '275 patent is invalid for failing to satisfy one or more of the statutory conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103 and 112.

87. ~~69.~~ Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

THIRD CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty Obligations Because the '275 Patent Is Axel Patents Are Unenforceable By Reason of Inequitable Conduct

(28 U.S.C. § 2201)

88. ~~70.~~ Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-~~69,87~~, inclusive, as if fully set forth herein.

89. ~~71.~~ The '275 patent is Axel patents are unenforceable as to Plaintiffs by reason of the inequitable conduct of Columbia in ~~the~~their prosecution of the '275 patent and enforcement.

90. ~~72.~~ In its dealings with the PTO, Columbia had a duty of candor, good faith, and honesty in seeking the '275 patent Axel patents. Columbia breached this duty, with the requisite intent to deceive, in at least the following ~~six ways~~: ~~(1) failing to disclose the Lewis & Srinivasan Letter, Presentation and Reference, the Goodgal CHO Transformation and Cotransformation Work during the prosecution of the Axel patents, or to disclose Willecke et al. 1976 during prosecution of the '216 patent; (2) signing and submitting declarations by Richard Axel, Michael H. Wigler, and Saul J. Silverstein which stated "we do not know and do not believe that this invention was ever known or used in the United States before our invention thereof" despite knowledge by one or more of Richard Axel, Michael H. Wigler and Saul J. Silverstein of the Lewis & Srinivasan Letter, Presentation and Reference, and/or the Goodgal CHO Transformation and Cotransformation Work; (3) misrepresenting the scope of the '216 patent and misleading the patent examiner; (24) failing to disclose statements~~

made to Congress that contradicted or rebutted positions taken during prosecution of the '275 patent; (35) misleading the '275 patent examiner into withdrawing double-patenting rejections based on the '017 patent; (46) further ~~misled~~misleading the examiners of the '275 patent and related '159 application to avoid double-patenting rejections based on the '017 patent; (57) failing to disclose material information or publications co-authored by named-inventors; and (68) failing to disclose the related, co-owned '636 patent, its prosecution history; and the PTO's rejection of substantially similar claims.

91. ~~73.~~ All of Columbia's omissions, misrepresentations, misleading statements and manipulations were material to the examination and patentability of the Axel patents and were made with intent to deceive, as inferred from the circumstances set forth above, and on information and belief. Columbia thereby committed inequitable conduct during prosecution of the '275 patentAxel patents, rendering the '275 patentthem unenforceable.

92. ~~74.~~ Because of the unenforceability of the '275 patentAxel patents, Plaintiffs desire a judicial determination and declaration that they do not owe the royalties and fees claimed by Columbia.

93. ~~This is an exceptional case, and Plaintiffs seek an award of attorneys' fees pursuant to 35 U.S.C. § 285.~~

94. ~~75.~~ Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

FOURTH CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty Obligations Because the '275 Patent Is Unenforceable By Reason of Prosecution Laches

(28 U.S.C. § 2201)

95. ~~76.~~ Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-~~75~~,94, inclusive, as if fully set forth herein.

96. ~~77.~~ Columbia engaged in unreasonable and unexplained delay in prosecution leading to the '275 patent. Columbia took 22 years from filing of the priority documents to

obtain the '275 patent. Columbia consciously delayed the prosecution of the '275 patent to obtain a patent with another 17 year term.

97. 78. During the period of this delay, the industry developed and matured in reliance on the fact that any additional patents arising under the common parent application would have been diligently prosecuted and, if directed to the same subject matter that had already been terminally disclaimed, would also be terminally disclaimed. As a result, enforcement of the '275 patent would be harmful and prejudicial to the public, including Plaintiffs.

98. 79. Because of, in part, the unenforceability of the '275 patent due to prosecution laches, Plaintiffs desire a judicial determination and declaration that they do not owe the royalties and fees claimed by Columbia.

99. 80. Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

FIFTH CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty Obligations Because the '275 Patent Is Unenforceable By Reason of Patent Misuse

(28 U.S.C. § 2201)

100. 81. Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-80,99, inclusive, as if fully set forth herein.

101. 82. The '275 patent is additionally unenforceable because Columbia sought unlawfully to extend its patent monopoly by claiming royalties not only for the period of the patent prior issued Axel patents, but also for the period from August 16, 2000 through September 24, 2002, after the '216, '665,665 and '017 patents had expired; and before the '275 patent issued.

102. 83. Because of the unenforceability of the '275 patent due to patent misuse, Plaintiffs desire a judicial determination and declaration that Plaintiffs do not owe the royalties and fees claimed by Columbia.

103. **84.** Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

SIXTH CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty

Obligations Based on Non-Infringement of the '275 Patent

(28 U.S.C. § 2201)

104. **85.** Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-84,103, inclusive, as if fully set forth herein.

105. **86.** Plaintiffs desire a judicial determination and declaration that they do not manufacture, use or sell any "Licensed Products" covered by a valid and enforceable claim of the '275 patent, and thus, they do not owe the royalties claimed by Columbia.

106. **87.** Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

SEVENTH CLAIM FOR RELIEF

Declaratory Judgment that Amgen and Immunex Have No Contractual Royalty

Obligations Based on Columbia's Failure to Perform Condition

(28 U.S.C. § 2201)

107. **88.** Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1-87,106, inclusive, as if fully set forth herein.

108. **89.** Columbia's contractual obligation to refrain from repressive practices, in derogation of Plaintiffs' rights under the License Agreement, was a condition to the obligations of Plaintiffs.

109. **90.** By Columbia's acts and omissions as alleged above, Columbia engaged in repressive practices, thus failing to fulfill this condition.

110. **91.** An actual controversy has arisen and now exists between Plaintiffs, on the one hand, and Columbia, on the other hand, concerning whether, as Columbia contends, Plaintiffs are required to pay additional royalties or, as Plaintiffs contend, their obligation to pay additional royalties is excused by reason of Columbia's failure to refrain from repressive

practices, and whether, as Columbia contends, it has validly terminated the Amgen license agreement or, as Plaintiffs contend, that agreement has not been validly terminated.

111. 92. Plaintiffs therefore desire a judicial determination and declaration of the parties' respective rights and duties with respect to Columbia's obligation to refrain from repressive practices, including a declaration that, apart from the requirements of the federal patent laws, Columbia engaged in repressive practices, within the meaning of the License Agreement, as a result of which payment of the royalties claimed by Columbia is excused, and that Columbia cannot use the failure of Plaintiffs to make those payments as a ground to terminate the License Agreement. A judicial declaration is necessary and appropriate at this time under the circumstances in order that Plaintiffs may ascertain their rights and duties under the License Agreement.

112. 93. Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

EIGHTH CLAIM FOR RELIEF

Declaratory Judgment that the '275 patent~~Patent~~ is Not Infringed, Is Invalid, and Is Unenforceable

(28 U.S.C. § 2201)

113. 94. Plaintiffs repeat, incorporate and reallege the allegations contained in paragraphs 1–93,~~–112~~, inclusive, as if fully set forth herein.

114. 95. Plaintiffs desire a judicial determination and declaration that they do not infringe any valid and enforceable claim of the '275 patent, e.g., through the manufacture, use, sell, offer for sale, or import of any products.

115. 96. Plaintiffs, therefore, respectfully seek judgment as hereinafter set forth.

116. 97. This is an exceptional case, and Plaintiffs seek an award of attorneys' fees pursuant to 35 U.S.C. § 285.

WHEREFORE, Plaintiffs pray for judgment against Columbia as follows:

a. a. For a declaration that Columbia's claims for royalties lack merit, and that no royalties or amounts are owed under the license agreements with Plaintiffs; and that Columbia may not and did not validly terminate the Amgen license agreements for Plaintiffs' failure to pay the royalties claimed agreement;

b. b. For recovery of amounts of royalty overpaid by plaintiffs through mistake;

b. c. For a declaration that Plaintiffs do not infringe the '275 patent and that the claims of the '275 patent are invalid and/or unenforceable;

c. d. For injunctive relief to prohibit Columbia from efforts to enforce against Plaintiffs the '275 patent or any obligation arising from the license agreements;

d. e. For attorneys' fees and costs of suit; and

e. f. For such other, further and additional relief as the Court may deem just and proper.

Dated: December 10, 2003. Dated: _____, 2004. Respectfully submitted,

~~ARTHUR WINEBURG~~
~~KIRKE M. HASSON~~
~~VICKI G. NORTON~~
~~JENNIE L. LA PRADE~~
~~PILLSBURY WINTHROP LLP~~

By _____
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Legend:

<u>Insertion</u>	
<u>Deletion</u>	
<u>Moved from</u>	
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<u>Moved cell</u>	
<u>Split/Merged cell</u>	
<u>Padding cell</u>	

Statistics:

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